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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,873	01/22/2002	Zhong-Ru Gan	020167-000130US	9316

20350 7590 01/09/2006

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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,873	GAN, ZHONG-RU	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *98,102-104,109-111,114-118,123,124,129-131,134-137,141,142,145 and146.* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *98,102-104,109-111,114-118,123,124,129-131,134-137,141,142,145 and146* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/26/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Claims 99-101, 119-122, 138-140, 143, and 144 were canceled, claims 98, 102-104, 109-111, 114, 115, 123, 124, 129-131, 134, and 135 were amended, and new claims 145 and 146 were added in the communication dated October 26, 2005. Claims 98, 102-104, 109-111, 114-118, 123, 124, 129-131, 134-137, 141, 142, 145 and 146 are pending and under consideration.

Information Disclosure Statement

A signed and initialed copy of the IDS paper filed October 26, 2005 is enclosed in this action.

Claim Objections/Rejections Withdrawn

The objection to the specification with regard to the "Table of Contents" is withdrawn in response to Applicants' amendment, as set forth in the Response filed October 26, 2005.

The objection to claims 98, 102-104, 109-111, 114, 115, 123, 124, 129-131, 134, and 135 for reciting the term "peptidyl" is withdrawn in response to Applicants' amendment, as set forth in the Response filed October 26, 2005.

The rejection of claims 98, 102-104, 109-111, 114-118, 123, 124, 129-131, 134-137, 141, and 142 under 35 U.S.C. §101 is withdrawn in response to Applicants' amendment, as set forth in the Response filed October 26, 2005.

The rejections of claims 98, 102-104, 109-111, 114-118, 123, 124, 129-131, 134-137, 141, and 142 under 35 U.S.C. §112, first paragraph is withdrawn in response to Applicants' amendment, as set forth in the Response filed October 26, 2005.

The rejection of claim 98 under 112, second paragraph is withdrawn in response to Applicants' amendment, as set forth in the Response filed October 26, 2005.

It is noted that all rejections of all canceled claims are rendered moot.

New issues are set forth below.

Specification

The disclosure is objected to because of the following informalities: There is a period where there should be a comma on p.12, line 17(original specification), i.e., "in the purification steps. which lead to a low yield of insulin".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 98, 102-104, 109-111, 114-118, 123, 124, 129-131, 134-137, 141, 142, 145 and 146 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with

the written description requirement. The claim(s) contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims encompass a recombinant nucleic acid encoding a chimeric protein, the chimeric protein comprising a peptide fragment of from 20 amino acids in length to 92 amino acids in length. The specification as filed does not provide a written description or set forth the metes and bounds of this phrase. The specification does not provide direction for the instant fragments encompassing the above-mentioned "limitation" as it is currently recited. The instant claims now recite a limitation which was not clearly disclosed in the specification as-filed, and now changes the scope of the instant disclosure as-filed. Such limitation recited in the present claims, which did not appear in the specification, as filed, introduces a new concept and violates the written description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide the location in the specification of sufficient written support for the "limitation" indicated above. The Examiner has concluded that there is no written support for the claimed range and thus, said range is considered to be new matter.

Claims 104 and 124 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter,

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 104 and 124 encompass a recombinant nucleic acid encoding a chimeric protein, the chimeric protein comprising a peptide fragment that is between 20 and 49 residues in length. The specification as filed does not provide a written description or set forth the metes and bounds of this phrase. The specification does not provide direction for the instant fragments encompassing the above-mentioned "limitation" as it is currently recited. The instant claims now recite a limitation which was not clearly disclosed in the specification as-filed, and now changes the scope of the instant disclosure as-filed. Such limitation recited in the present claims, which did not appear in the specification, as filed, introduces a new concept and violates the written description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide the location in the specification of sufficient written support for the "limitation" indicated above. Applicant's amendment, in the communication dated October 26, 2005, does not provide sufficient direction for the written description for the above-mentioned limitation of claim 104 and 124. In said amendment, Applicant asserts, "Support for this subject matter is found in previous claim 139." However, claim 139 was introduced by the amendment dated October 15, 2004 and was thus not a part of the original disclosure. Nowhere in the specification is there any mention requiring the first peptide fragment to be "between 20 and 49

residues in length." The Examiner has concluded that there is no written support for the claimed range and thus, said range is considered to be new matter.

Claims 118, 123, 124, 129-131, 134-137, 141, and 142 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated or cultured cell comprising an expression vector that expresses a nucleic acid, does not reasonably provide enablement for a cell comprising a nucleic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Examiner has interpreted the claims as reading on isolated host cells, as well as host cells intended for gene therapy. The specification of the instant application teaches a variety of vector-host cell systems (p.17, line 25-p.19, line 4, original specification). At p.19, lines 4-8, the specification teaches, "Any of the methods previously described for the insertion of DNA fragments into a vector may be used to construct expression vectors containing a chimeric gene consisting of appropriate transcriptional/translational control signals and the protein coding sequences. These methods may include in vitro recombinant DNA and synthetic techniques and *in vitro* recombinant DNA and synthetic techniques and *in vivo* recombinants (genetic recombination). Further, at p.22, lines 8-9, the specification teaches, "The nucleic acid sequence encoding the chimeric protein disclosed in Section 4.2, or fragments, analogs or derivatives thereof, can be mutated *in vitro* or *in vivo*."

However, there are no methods or working examples disclosed in the instant application whereby a cell is demonstrated to express the chimeric protein *in vivo*. The disclosure in the specification is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Relevant literature teaches that since 1990, about 3500 patients have been treated via gene therapy and although some evidence of gene transfer has been seen, it has generally been inadequate for a meaningful clinical response (Phillips, A., J Pharm Pharmacology 53: 1169-1174, 2001; abstract). Additionally, the major challenge to gene therapy is to deliver DNA to the target tissues and to transport it to the cell nucleus to enable the required protein to be expressed (Phillips, A.; p.1170, ¶ 1). Phillips also states that the problem with gene therapy is two-fold: 1) a system must designed to deliver DNA to a specific target and to prevent degradation within the body, and 2) an expression system must be built into the DNA construct to allow the target cell to express the protein at therapeutic levels for the desired length of time (p.1170, ¶ 1). Therefore, undue experimentation would be required of the skilled artisan to introduce and express a recombinant nucleic acid of the current invention into the cell of an organism. Additionally, gene therapy is unpredictable and complex wherein one skilled in the art may not necessarily be able to introduce and express said nucleic acid in the cell of an organism or be able to produce the encoded gene product in that cell.

Due to the large quantity of experimentation necessary to introduce and express said nucleic acid in a cell of an organism for therapy, the lack of direction/guidance presented in the specification regarding how to introduce the nucleic acid in the cell of

an organism to be able produce the chimeric protein, the absence of working examples directed to same, the complex nature of the invention, and the state of the prior art which establishes the unpredictability of transferring genes into an organism's cells, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope. (Please note that this issue could be overcome by amending the claims to recite, for example, "An isolated host cell...").

Conclusion

No claims are allowed.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 8:30AM to 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gregory S. Emch, Ph. D.
Patent Examiner
Art Unit 1649
January 4, 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER